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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/965,473	09/26/2001	Terry A. Guinan	P1046 US	2802

7590 09/25/2003

Medtronic AVE, Inc.
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Santa Rosa, CA 95403

EXAMINER

BAXTER, JESSICA R

ART UNIT	PAPER NUMBER
3731	

DATE MAILED: 09/25/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

NYK

Office Action Summary	Application No.	Applicant(s)
	09/965,473	GUINAN ET AL.
Examiner	Art Unit	
Jessica R Baxter	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 08 July 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-18 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless —

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 2, 4, 6, 7, 10, 11, 12, 13, 15 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,048,350 to Vrba.

Regarding claims 1, 6, 7, 10 and 11, Vrba discloses a catheter comprising an elongate shaft (shaft 12) and a balloon having a flexible wall (balloon 16), an intermediate body (16B), proximal and distal cones (16A and 16C), proximal and distal ends, and at least one circumferential groove formed of the balloon wall adjacent a transition between the intermediate body and a cone (FIG. 2 spaces 22), and a balloon expandable stent (stent 20).

Regarding claim 2, Vrba discloses that the circumferential groove has a shape selected from the C-shapes, U-shapes, W-shapes, and open-sided polygons (FIG. 2 spaces 22).

Regarding claims 4, 12, 13 and 18, Vrba discloses that the at least one circumferential groove is at least partially filled with a flexible material that is adhered to the balloon (Column3 lines 53-62).

Regarding claim 15, Vrba discloses a method comprising the steps of providing a catheter having an elongate shaft (shaft 12), mounting a balloon around a distal end of the shaft, collapsing the balloon around the catheter shaft (FIG. 1 and Column 3 lines 24-36),

and mounting a balloon expandable stent in a radially compressed configuration around the intermediate body of the balloon (Column 3 lines 29-36).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Vrba '350 in view of U.S. Patent No.6,254,608 to Solar.

Vrba discloses the claimed invention except for the flexible material comprising a foamed material. Solar teaches that a foamed material is used for bonding the stent to the catheter to allow the stent to become embedded in the balloon in order to protect the anatomical passageways during delivery of the stent and prevent the stent from slipping without the use of a protective sheath (Column 3 line 44 – Column 4 line 2 and Column 5 lines 20-24). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the balloon catheter of Vrba with the foamed material of Solar in order to protect the anatomical passageways during stent delivery and prevent the stent from slipping off the balloon without the use of a protective sheath.

1. Claims 3, 8, 9, 14, 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vrba '350 in view of U.S. Patent No. 6,293,959 to Miller et al.

Vrba discloses the claimed invention except for the balloon having a deflated profile where the distal and proximal cones have a larger deflated profile than the intermediate

body. Miller teaches that the enlarged proximal and distal cones are provided to provide a nest portion for the stent so that friction is minimized and adverse contact between the ends of the stent and the vessel wall is minimized (Column 4 lines 36-45). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the balloon of Vrba with the enlarged proximal and distal cones of Miller in order to provide a nest portion for the stent in order to minimize friction and adverse contact between the stent ends and the vessel wall.

Response to Arguments

1. Applicant's arguments filed July 8, 2003 have been fully considered but they are not persuasive.

Applicant argues that Vrba' 350 does not disclose a circumferential groove in the balloon wall adjacent a transition between the intermediate body and a cone. In FIG.2, there are clearly grooves in the balloon wall between the cone shape and the intermediate body. Applicant argues that these grooves are stent mounting bodies (24) that extend beyond the diameter of the balloon in the deflated condition. However, there are no claim limitations which require that the grooves are in both the inflated and deflated conditions of the balloon.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica R Baxter whose telephone number is 703-305-4069. The examiner can normally be reached on M-F 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on 703-308-2496. The fax phone numbers for the organization

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where this application or proceeding is assigned are 703-872-9302 for regular communications and 703-872-9302 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Jessica R Baxter
Examiner
Art Unit 3731

jrb

September 21, 2003


MICHAEL J. MILANO
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700